UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 17 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Daniel Liebowitz
Regulatory Compliance Manager, Americas
Product Stewardship and Regulatory Affairs
Allnex, 78 Rivergate Drive
Wilton, CT 06897

CONTAINS NO CBI

Re: Prenotice Communication 7015

Dear Mr. Liebowitz

You recently submitted, then withdrew, a Low Volume Exemption request (LVE) for a material which you already make as a nonisolated intermediate in a process your company has in this country and which you also manufacture as a 'solely for export' material for use in Europe. You explained to Dave Schutz of my staff that your facility had made a batch of material intended for export to your European users and compliant with the regulations controlling materials for export. You then found that it did not meet your customers' specifications, and you now have the off spec material in storage in US. It was your hope that by sending the material to your European facility, then importing it, you could enable it to be reworked in this country and incorporated into the US process for which you now make the material as a nonisolated intermediate. You also expressed the hope that an LVE, if in place, could enable your firm to rework any future off spec batches for incorporation into your process here, to avoid waste of this expensive material.

TSCA regulations state that material which had been manufactured with the intent that it be for export only can be used for research and development under the exemption from TSCA listing if it meets the requirements described at 40 CFR §§ 720.36 and 720.78. The definition of manufacture solely for export is found at 40 CFR §720.3(s): "...manufacture or import for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

(1) Distribution in commerce is limited to purposes of export or processing solely for export as defined in Sec. 721.3 of this chapter.

(2) The manufacturer or importer, and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in Sec. 721.3 of this chapter), **may not use the substance except in small quantities solely for research and development in accordance with Sec. 720.36.**"

These regulations covering material made solely for export were not written with the purpose of permitting it to be repurposed for use in this country. It is the Agency's view, however, that the limitation in §720.3(s)(2) applies to diversion to domestic uses of material manufactured with the intent that it be solely for export, and that was not actually exported. Import is treated as new manufacture by our statute, and thus your suggestion to export the material to your European facility, then reimport if the substance clears §5 review, would eliminate the §720.3(s)(2) barrier.

Please be aware that if you wait to export the product until after a §5 notice has been successful that EPA would not consider that product to have been manufactured solely for export. However, if you export the product before it has cleared § 5 review (and preferably before a §5 submission has been filed with EPA), and with the understanding that there is no guarantee that § 5 review will be successful, and that if § 5 review is not successful that the product may not be allowed back into the U.S., the Agency would consider the product to have been manufactured for export. As a consequence, this stratagem for rescuing off spec material could be successful only once, and if you are to be able to reprocess off spec material after this single time it will have to be on the basis of a successful §5 submission.

Such subsequent import of the material would then be considered manufacture. Thus if a §5 notice – which can be a LoREX, an LVE, or a PMN – has been later filed for the material and the material has cleared §5 review, import can take place under any conditions that may have been set during the review that notice.

As you consider a §5 notice, I want to remind you that for purposes of an LVE, the volume limit applies to all substance manufactured, even that which will be sent abroad. Consequently, if your company uses an LVE for the purpose of enabling the rework of the material currently in storage, you would be limiting yourself going forward to the 10 metric ton yearly limit which applies to each LVE for both domestic and international uses. Your discussion of the material with Mr. Schutz suggests that this would not be adequate, and it was for this reason that you withdrew your earlier application. A PMN or a LoREX would not impose a quantitative restriction, so you may want to consider filing one of them. Further, a PMN or LoREX can enable reprocessing of any off spec material which may be manufactured in future, and there would be no need to export/reimport in such case.

It is prudent, when material which was made prior to its review under TSCA is put into TSCA-regulated commercial use, to document the fact that the manufacture was in fact compliant – in the case of manufacture solely for export by showing that the provisions of the regulations governing 'solely for export' material were satisfied - and to maintain that documentation with company records for this material. In all of these cases, the intent at time of manufacture is important in determining whether the submitter's conduct is lawful, so maintenance of clear records on intent can only help the submitter. I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of my staff, on 202-564-9262.

Sincerely,

[redacted]

Greg Schweer, Chief
New Chemicals Management Branch 7405M
Chemical Control Division

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CONCURRENCES

SYMBOL	7405M	7405	7405M					
SURNAME	DSN	DS	Schutz					
DATE	2013-09-26	9/26/13	10/17/13					

OFFICIAL FILE COPY

Lee, Brian

From: Sadowsky, Don
Sent: Wednesday, September 11, 2013 7:15 AM
To: Schutz, David; Seltzer, Mark
Cc: Lee, Brian; Coutlakis, Anna
Subject: RE:

Dave –

We discussed your question during our biweekly TSCA Practice Group meeting (in fact it took the whole hour). The meeting was helpful to my understanding, though not giving as clear as result as I would have liked. The upshot is that the company's idea of exporting the batch with the possibility of bringing it in if Section 5 obligations are cleared may not be such a bad idea.

As you know, I was considering an argument that the company would be able to begin processing one sec. 5 obligations were met, on the theory that the original manufacture, having happened for the purposes of export, did not require a sec. 5 notice. There are actually three problems with my construct:

1. (I should have remembered this:) Processing does not require a PMN, only manufacture/import. While this is not a problem for the company, it could be a problem for EPA because (see 2 below)
2. If a company that intended to export a new chemical substance when it manufactures the substance does not require a PMN to then do anything else with it, the PMN requirement disappears for that manufactured batch, along with any opportunity to control that batch. In addition, it might prevent EPA from designating whatever is done with that batch as a SNU. There could be all kinds of mischief.
3. 12(a) has a curious structure in that while manufacture which was for export purposes at the time could later be taken out of the 12(a) exemption because of later activities. The manufacture for export exemption applies "unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States". This means that if the company files, say, a PMN and then processes the substance, that very act of processing makes the earlier manufacture no longer for export. And even though post-PMN manufacture would be legal, the earlier manufacture would no longer be. While OPPT might consider interpreting TSCA to not give this result, it does increase the probability that companies could too easily avoid section 5 obligations.

I had told you over the phone that exporting to bring back after sec. 5 obligations have been met was not a viable obligation because export with the intent of bringing the product back to the U.S. would be distribution in commerce for use in the U.S. My colleagues suggested an alternate interpretation: the company would be exporting the product with the possibility of bringing it back to the U.S., should it clear section 5 review. While this is a possible interpretation of 12(a), it is not certain to survive a challenge (though I doubt there would be such a challenge), but more importantly OPPT should give some thought as to whether interpreting intent to bring back into the country subject to an uncertain section 5 clearance process as not being "manufactured, processed, or distributed in commerce, for use in the United States" might in some way come back to bite you in another circumstance.

We also discussed whether OECA, while unlikely to grant enforcement discretion, would consider a slap on the wrist. We would also be interested in knowing what happens when a domestic company manufactures a new chemical substance without going through section 5 review and then self-confesses. Does the Agency require the company to destroy the already-manufactured batches?

Hopefully this is clear. Let me know if you have any questions.

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. 20460
(202) 564-5638

Schutz, David

From: Liebowitz, Daniel [Daniel.Liebowitz@allnex.com]
Sent: Thursday, September 05, 2013 3:08 PM
To: Schutz, David
Subject: RE: LVE L13-0614 (TS CR13P6)

Withdrawal submitted via CDX.

From: Schutz, David [mailto:Schutz.David@epa.gov]
Sent: Thursday, September 05, 2013 2:51 PM
To: Liebowitz, Daniel
Subject: RE: LVE L13-0614 (TS CR13P6)

Kathy Schechter asked for this in CDX as a support form. Dave Schutz

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From: Liebowitz, Daniel [mailto:Daniel.Liebowitz@allnex.com]
Sent: Thursday, September 05, 2013 2:24 PM
To: Schutz, David
Cc: Schechter, Kathryn; Amagai, Bryan
Subject: RE: LVE L13-0614 (TS CR13P6)

Dave,

Based on our phone discussion this afternoon, I am requesting withdrawal of the LVE (L13-0614). As discussed, I am still interested in the guidance letter you are drafting.

Regards,
Dan

From: Schutz, David [mailto:Schutz.David@epa.gov]
Sent: Wednesday, September 04, 2013 3:54 PM
To: Liebowitz, Daniel
Cc: Schechter, Kathryn; Amagai, Bryan
Subject: RE: LVE L13-0614 (TS CR13P6)

I'm working on a letter for you. At this point, it looks very unlikely that an LVE is going to be a good strategy for you. In case that turns out not to be true, you should request an extension on this LVE – somewhere in the fifteen to thirty days range. Dave Schutz

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From: Liebowitz, Daniel [mailto:Daniel.Liebowitz@allnex.com]
Sent: Tuesday, September 03, 2013 11:29 AM
To: Schutz, David
Subject: RE: LVE L13-0614 (TS CR13P6)

David,

Has a decision been made regarding LVE L13-0614?

Dan

From: Liebowitz, Daniel
Sent: Thursday, August 08, 2013 1:21 PM
To: 'Schutz.david@Epa.gov'
Subject: LVE L13-0614 (TS CR13P6)

David,

As requested, I am providing a description of the proposed scenario for submission of the referenced LVE:

Allnex USA Inc. currently manufactures the substance described in the referenced LVE under the "Export Only" exemption for use by one of our European manufacturing sites for the production of a final coating resin product. The U.S. manufacturing site also manufactures this substance as a non-isolated intermediate for manufacture of the final coating resin at the U.S. site. An off-spec batch of this substance was recently manufactured, isolated and is currently in storage. This material cannot be used by the European site. It can be re-worked at the U.S. site and used to make the final coating resin. However, since this material was manufactured for "Export Only", it cannot be re-worked and used for commercial production in the U.S. Allnex has submitted a LVE to allow the U.S. site to re-work this material and use it for commercial manufacture. The proposed course of action is to export the material to one of our sites outside the U.S., and re-import for re-working it once the LVE has cleared EPA review. This is not a planned routine procedure that we would expect to conduct more than once. However, this would allow Allnex to avoid wasting this expensive intermediate and would also allow this to occur in the future if an off-spec batch is produced. This would be limited to 10,000 kg/year.

Regards,
Dan

Daniel Liebowitz
Regulatory Compliance Manager, Americas
Product Stewardship & Regulatory Affairs

Allnex

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ROUTING AND TRANSMITTAL SLIP TO: (Name, office symbol, room number, building, Agency/Post)	Date 2013-09-26 Initials DS	Date
Brian Lee	BL	9/27/13
Greg Schweer	GA	9/27/13
Dave Schutz		

A few edits needed ✓

	Action		**Note and Return**
X	**Approval**		**Per Conversation**
	As Requested		**Prepare Reply**
	Circulate		**See Me**
	Comment	X	**Signature**
	Coordination		

REMARKS

Don Sadowsky has looked this over and blessed it, but I'm not eager to put him in the review loop.

PC 7015 NOT CBI

FROM: (Name, org symbol, Agency/Post)	Room No. – Bldg. **4419J**
Dave Schutz	Phone No. **564-9262**